JUL - 2 2002

510(k) Summary

K021829

1. Company Identification

Eastman Kodak Company
343 State Street
Rochester, NY 14650
585-724-5910

2. Contact Person

Carol C. Ryerson
Regulatory & Clinical Affairs Manager

3. 510(k) Summary Preparation Date

May 31, 2002

4. Device Name

Kodak DirectView CR Long-Length Imaging System

5. Device Classification

Class II

6. Intended Use

The KODAK DirectView CR Long-Length Imaging System is used with the KODAK DirectView CR 800/ CR 900 Systems which are compact laser scanners capable of reading the latent image formed on a storage phosphor imaging plate and producing a digital image for projection radiology applications. The Long Length Imaging feature is used for examinations of long areas of anatomy such as the leg and spine.

7. Description of Device

The Kodak DirectView CR Long-Length Imaging System extends the capability of the Kodak CR 800 and CR 900 computed radiography systems to allow the capture of long length images with an image area up to 130 cm high x 43 cm wide. Individual CR images are limited to the size of a CR cassette, the largest being 35 x 43 cm. The Kodak Long-Length Imaging System includes a vertical cassette holder, which can hold up to four CR screens and image stitching software, which will operate on the CR 800 or CR 900 system. Image capture is accomplished using standard x-ray equipment and technique. The CR screens are

then removed form the vertical cassette holder and placed in the CR 800 or CR 900 system to be scanned. The image stitching software processes the images correcting for magnification, translation, and rotation differences among the images, eliminates redundant pixels in the overlap region and stitches together the individual images. The resulting single composite image covers an image area of up to 130 cm x 43 cm, and can be stored to a PACS workstation or printed to film using a laser imager.

8. Substantial Equivalence

The Kodak DirectView CR 800/ 900 System is being modified with addition of a software module (Kodak DirectView CR Long-Length Imaging Software) and hardware accessory (Kodak DirectView CR Long-Length Vertical Cassette Holder) to be used with the software. The purpose of these modifications is to enable the use of multiple cassettes to obtain images of long areas of anatomy, up to 130 cm in length, and then to present the image as a single composite image. The CR cassettes and the radiographic techniques remain unchanged. The intended use of the Kodak DirectView CR 800/ 900, previously stated, as "compact laser scanners capable of reading the latent image formed on a storage phosphor imaging plate and producing a digital image for projection radiology applications" remains unchanged. The modification does not affect the intended use of the device or alter the fundamental scientific technology of the device.

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
9200 Corporate Boulevard
Rockville MD 20850

JUL - 2 2002

Ms. Carol C. Ryerson
Regulatory & Clinical
Affairs Manager
Eastman Kodak Company
343 State Street
ROCHESTER NY 14650

Re: K021829
Trade/Device Name: Kodak Direct View CR
Long-Length Imaging System
Regulation Number: 21 CFR 892.1630
Regulation Name: Electrostatic x-ray
imaging system
Regulatory Class: II
Product Code: 90 MQB
Dated: May 31, 2002
Received: June 4, 2002

Dear Ms. Ryerson:

We have reviewed your Section 510(k) premarket notification of intent to market the device referenced above and have determined the device is substantially equivalent (for the indications for use stated in the enclosure) to legally marketed predicate devices marketed in interstate commerce prior to May 28, 1976, the enactment date of the Medical Device Amendments, or to devices that have been reclassified in accordance with the provisions of the Federal Food, Drug, and Cosmetic Act (Act) that do not require approval of a premarket approval application (PMA). You may, therefore, market the device, subject to the general controls provisions of the Act. The general controls provisions of the Act include requirements for annual registration, listing of devices, good manufacturing practice, labeling, and prohibitions against misbranding and adulteration.

If your device is classified (see above) into either class II (Special Controls) or class III (PMA), it may be subject to additional controls. Existing major regulations affecting your device can be found in the Code of Federal Regulations, Title 21, Parts 800 to 898. In addition, FDA may publish further announcements concerning your device in the Federal Register.

Please be advised that FDA's issuance of a substantial equivalence determination does not mean that FDA has made a determination that your device complies with other requirements of the Act or any Federal statutes and regulations administered by other Federal agencies. You must comply with all the Act's requirements, including, but not limited to: registration and listing (21 CFR Part 807); labeling (21 CFR Part 801); good manufacturing practice requirements as set forth in the quality systems (QS) regulation (21 CFR Part 820); and if applicable, the electronic product radiation control provisions (sections 531-542 of the Act); 21 CFR 1000-1050.

This letter will allow you to begin marketing your device as described in your 510(k) premarket notification. The FDA finding of substantial equivalence of your device to a legally marketed predicate device results in a classification for your device and thus, permits your device to proceed to the market.

If you desire specific advice for your device on our labeling regulation (21 CFR Part 801), please contact the Office of Compliance at one of the following numbers, based on the regulation number at the top of this letter:

8xx.1xxx	(301) 594-4591
876.2xxx, 3xxx, 4xxx, 5xxx	(301) 594-4616
884.2xxx, 3xxx, 4xxx, 5xxx, 6xxx	(301) 594-4616
892.2xxx, 3xxx, 4xxx, 5xxx	(301) 594-4654
Other	(301) 594-4692

Additionally, for questions on the promotion and advertising of your device, please contact the Office of Compliance at (301) 594-4639. Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21 CFR Part 807.97). Other general information on your responsibilities under the Act may be obtained from the Division of Small Manufacturers, International and Consumer Assistance at its toll-free number (800) 638-2041 or (301) 443-6597 or at its Internet address http://www.fda.gov/cdrh/dsma/dsmamain.html.

Sincerely yours,

Nancy C. Brogdon

Nancy C. Brogdon
Director, Division of Reproductive,
Abdominal, and Radiological Devices
Office of Device Evaluation
Center for Devices and Radiological Health

Enclosure

Statement of Intended Use

510(k) Number (if known): K021829

Device Name: Kodak DirectView CR Long-Length Imaging System

Indications for Use: The KODAK DirectView CR Long-Length Imaging System is used with the KODAK DirectView CR 800/ CR 900 Systems which are compact laser scanners capable of reading the latent image formed on a storage phosphor imaging plate and producing a digital image for projection radiology applications. The Long-Length Imaging feature is used for examinations of long areas of anatomy such as the leg and spine.

Concurrence of CDRH, Office of Device Evaluation

Prescription Use ✓ OR Over-the counter use_____
(per 21 CFR 801.109)

David G. Hoffman

(Division Sign-Off)
Division of Reproductive, Abdominal,
and Radiological Devices
510(k) Number K021829